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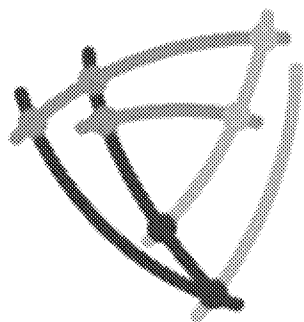
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Sent: 8/3/2021 12:25:31 PM
To: Robinson, Jeffrey [Robinson.Jeffrey@epa.gov]; Verhalen, Frances [verhalen.frances@epa.gov]
CC: Schoellkopf, Lynde [Schoellkopf.Lynde@epa.gov]; Hood, Brianna [Hood.Brianna@epa.gov]
Subject: Opinion: Suit Against Medical-Product Sterilization Firm a Dangerous Abuse of State Authority, KRWG, 8/1/2021

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Suit Against Medical-Product Sterilization Firm a Dangerous Abuse of State Authority

By PAUL GESSING-RIO GRANDE FOUNDATION • JUL 31, 2021

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Sterigenics®
A Sotera Health company

Commentary: On December 22, 2020, Attorney General Balderas filed suit against product-sterilization company Sterigenics, alleging that ethylene oxide (EtO) emissions

from its plant in Santa Teresa were creating a public nuisance and asking the court to enjoin the emissions.

[You can read the AG's complaint here.](#)

[Here is one informative report on lawsuit.](#)

According to the federal court docket (Sterigenics had initially removed the case from state to federal court but the federal court refused to accept the removal and sent it back to the state court), private contingent-fee lawyers from the [Delaware-based firm Grant & Eisenhofer](#) are working with Balderas on the suit.

- Such state AG-contingent fee attorney arrangements have become commonplace. The alliances raise questions as to who is really in charge of litigating on behalf of the public interest, and what really motivates the private plaintiffs' lawyers.)
- [Grant & Eisenhofer is advancing hundreds of private lawsuits against Sterigenics.](#) Having a state AG action be successful in enjoining EtO emissions would be a boon to the firm's private litigation efforts.

Sterigenics has operated the Santa Teresa plant since 1989. It sterilizes surgical kits, preoperative skin products, syringes, tubing, and other medical equipment using EtO. 50% of the devices sterilized nationally are sterilized with EtO. [An Albuquerque Journal](#) story noted that the state hospital association wrote to Gov. Grisham explaining the consequences if the state shut down the plant. The story also relates an affidavit from a device company microbiologist noting the suit's impact on its product and patients.

The nuisance that the suit alleges is from "uncontrolled" emissions of EtO that are allegedly increasing cancer risks in the areas around the plant.

- The state's complaint offers no evidence of actual harm. It only recited what U.S. EPA has said about EtO emissions, which are deeply flawed (see pp 9-10 of Sterigenics brief).
- The "uncontrolled" emissions allegedly occur a number of ways, including the opening and closing of facility doors and when customers visit the plant and carry away their sterilized products.
- The complaint essentially demands that the emissions limit Sterigenics must meet is *zero*

As explained well in the trade associations' *amicus* briefs, companies like Sterigenics that use EtO in their sterilization must comply with detailed regulations issued by FDA, EPA, OSHA, and the state environmental regulatory agency. Those agencies undertake meticulous efforts to craft and issue those regulations and employ issue experts in the process of setting emissions limits.

- A judicial verdict implementing the AG's zero-emissions approach would directly conflict with federal and state regulations, placing the AG and the court into the role of environmental regulators, a role they are entirely unfit to fulfill.
- That outcome creates a compliance nightmare for Sterigenics and bodes ominously for any business in New Mexico or businesses looking to locate offices in New Mexico.

On June 29, District Judge Beyer granted the state's motion for a preliminary injunction, prohibiting "continued uncontrolled emissions of EtO." It's unclear as of this moment what has occurred in the meetings between the state and Sterigenics that the court ordered with a goal of creating a "monitoring protocol."

Bottom line: The state AG isn't doing the state, the state's business community, or New Mexicans any favors by pursuing this regulation-by-litigation effort to usurp control over EtO and its use from federal and state agencies whose authority over EtO emissions are firmly bound in statutes. General Balderas' lawsuit will stoke fear over miniscule EtO emissions and device sterilization and any victories in the suit could help the suit's masterminds in the private contingent-fee lawyer' bar turn EtO into the next asbestos.